Citation:

Palmer JR, Boggs DA, Krishnan S, Hu FB, Singer M, Rosenberg L. Sugar-sweetened beverages and incidence of type 2 diabetes mellitus in African American women. *Arch Intern Med.* 2008 Jul 28;168(14):1487-92.

PubMed ID: 18663160

Study Design:

Prospective Cohort Study

Class:

B - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To examine the association between consumption of sugar-sweetened beverages, weight gain, and incidence of type 2 diabetes mellitus in African American women.

Inclusion Criteria:

- Women aged 21 - 69 years who responded to a questionnaire sent to them in 1995

Exclusion Criteria:

Women who had reported any of the following between 1995 and 2005:

- Diabetes (n=2920) or gestational diabetes (n=638) at baseline
- Myocardial infarction or stroke (n=806) at baseline
- Cancer (n=1146) at baseline
- Pregnant (n=956) at baseline
- Younger than 30 years at the end of follow-up in 2005 (n=1362)
- Missing data on height or weight at baseline (n=474)
- Incomplete dietary questionnaire or left more than 10 dietary questions blank (n=2982)
- Implausible energy intake values (<500 or >3800 kcal; n=3050)
- Missing data on soft drink consumption in 1995 (n=417)

Description of Study Protocol:

Recruitment

Women responded to questionnaires mailed to subscribers of *Essence* magazine, members of several African American professional organizations, and friends or relatives of early respondents.

Design

The Black Women's Health Study is an ongoing prospective cohort study.

Blinding used (if applicable): Not mentioned

Intervention (if applicable): Not applicable

Statistical Analysis

- Person-years of follow-up = number of years from enrollment to first diagnosis of diabetes, death, loss to follow-up, or completion of the 2005 questionnaire; for participants younger than 30 years old at the start of the study had follow-up beginning the year they turned 30.
- Age- and time-stratified Cox proportional hazard models were used to calculate incidence rate ratios (IRRs).
- Multivariate models included terms for age; questionnaire cycle; family history of diabetes,; cigarette smoking; physical activity; years of education; glycemic index of the diet; and intake of coffee, red meat, processed meat, and cereal fiber.
- Tests for linear trend across categories of drink consumption were done by adding an ordinal variable representing frequency of consumption to the multivariate models.

Data Collection Summary:

Timing of Measurements

- Baseline (1995): height and weight, demographics, reproductive history, medical history, use of medications, use of cigarettes and alcohol, and usual diet (food and beverage intake - obtained through 68-item Block National Cancer Institute food frequency questionnaire (FFQ), short-form)
- Every two years: lifestyle factors and other exposures; new occurrences of serious illnesses, including diabetes (total of 5 cycles of follow-up)
- 2001 - usual diet

Dependent Variables

- Incident cases of type 2 diabetes - classified if they reported diabetes on any of the follow-up questionnaires and had not previously reported a diagnosis of diabetes.

Independent Variables

- Beverage intake - calculated as the number of medium servings consumed per week; based on 3 questions of how often they drank "regular soft drinks (not diet soda) "orange juice or grapefruit juice," and "other fruit juices, fortified fruit drinks, Kool-Aid" with frequency and amount options
- For each of sugar-sweetened soft drinks and fruit drinks, participants were classified into 5 mutually exclusive categories: those who consumed ≤ 1 drink/wk in 1995 and had not changed their intake; those who consumed ≤ 1 drink/wk in 1995 and increased to ≥ 1 drinks/day; those who consumed ≥ 1 drink/day in 1995 and did not change; those who consumed ≥ 1/day in 1995 and reduced their intake to ≤ 1 drink/wk in 2001; and those who did not fit into any of the previous categories.

Control Variables

- Self-reported height and weight were used to calculate body mass index (BMI)
- Level of education
- Cigarette smoking
- Alcohol consumption
- Physical activity
- Hormone use
- Family history of diabetes
- Glycemic index of diet
- Intake of coffee, red meat, processed meat, and cereal fiber
- Total energy intake

Description of Actual Data Sample:

Initial N: 59,000 women

Attrition (final N): 43,960 women in present analysis (1995-2005 with exclusions; 80% response rate for each follow-up time point)

Age: 21 - 69 years at baseline

Ethnicity: African Americans

Other relevant demographics: At baseline -- ~35% had a family history of diabetes; BMI averaged about 28; ~45% said they did at least one hour a week of physical activity; about 16% were current smokers; ~15% had 12 years or less of education; and 1.5 alcoholic drinks per week

Anthropometrics

Location: Nationwide - United States

Summary of Results:

Key Findings

- 2,713 incident cases of type 2 diabetes during 338,884 person-years of follow up were identified
- Incidence of type 2 diabetes was higher with higher intake of both sugar-sweetened soft drinks and fruit drinks. After adjusting for confounding variables including other dietary factors, the IRR for 2 or more soft drinks per day was 1.24 (95% CI, 1.06-1.45, P=.002 for trend) and 1.31 (95% CI, 1.13-1.52, P=.001 for trend) for fruit drinks.
    - Women who consumed 2 or more soft drinks per day had a 24% increase in incidence relative to women who drank less than 1 soft drink per month.
    - Women who consumed 2 or more fruit drinks per day had a 31% increase in incidence relative to women who drank less than 1 fruit drink per month.
- The majority of participants gained weight during the 6-year interval. In multivariate models that included terms for change in other risk factors, the greatest weight gain was seen in those who increased their consumption of soft drinks (mean weight gain, 6.8 kg). The lowest mean weight gain (4.1 kg) occurred among those who decreased their consumption of soft drinks ($P < 0.001$ for the comparison of those with the greatest and lowest mean weight gains). Weight loss in the 6-yr interval was most common (24%) among women who decreased their intake of sugar-sweetened soft drinks and least common (16%) among those

who increased consumption or were already consuming 1 or more soft drinks per day and did not cut back. The association between changes in consumption and weight gain was weaker for sweetened fruit drinks.

Other Findings

- At baseline, 17% of participants drank at least 1 sugar-sweetened soft drink per day, 32% drank at least 1 sweetened fruit drink per day, and 22% had at least 1 glass of orange or grapefruit juice per day.
- Intake of sugar-sweetened soft drinks was inversely related to age, physical activity, years of education, and cereal fiber intake and positively related to BMI, cigarette smoking, energy intake, glycemic index, and intake of red meat and processed meat. Intake of sugar-sweetened fruit drinks was also inversely associated with age and positively associated with total calorie intake and intake of processed meats.
- Consumption of orange and grapefruit juice was not associated with diabetes risk (p=.28 for trend).

Author Conclusion:

Regular consumption of sugar-sweetened soft drinks and fruit drinks is associated with an increased risk of type 2 diabetes mellitus in African American women. Reducing consumption of soft drinks is a concrete step that women may find easier to achieve than other approaches to weight loss.

Reviewer Comments:

Strengths:

- *Large size cohort with large number of incident diabetes cases*
- *Focus on African American women, a population with high rates of type 2 diabetes but understudied*
- *Confounding variables accounted for*

Weaknesses:

- *Reliance on self-reported beverage and diet information*
- *Convenience sample*
- *Beverage consumption was based on baseline report and individuals who changed their drinking patterns may have been misclassified as to exposure*
- *Type 2 diabetes incident cases based on self-report (although a subportion was verified to be 94% accurate)*
- *No cause and effect*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	N/A

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	No
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes

3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	Yes
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	N/A

6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	N/A
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	???
7.5.	Was the measurement of effect at an appropriate level of precision?	???
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes

9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes